OCA consumer register

A supplement to Consumer News

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Speak up & be heard

CONSUMER REGISTER lists summaries of major consumer proposals before Federal agencies. If you wish to submit written comments, include your name & address, state the name & *Federal Register* citation of the proposal on which you are commenting and explain your views briefly & clearly.

Cosmetics

Food & Drug Administration (FDA) has issued a final order requiring manufacturers of all cosmetics to list ingredients on product labels. The new labeling requirement will cover all cosmetic labels ordered from printers after March 31, 1974, & all cosmetic products labeled after March 31, 1975. These dates are to allow manufacturers time to clear out current stocks, redesign & order new labels.

Under the labeling requirement:

- Cosmetic ingredients must be listed in descending order of prevalence & by standardized names, based on the dictionary of cosmetic ingredients developed by the Cosmetic, Toiletries & Fragrances Association. Fragrances & colors can be labeled simply as fragrances & colors.
- The labeling declaration must be in letters not less than 1/16 of an inch.
- A tag or card with the required ingredient information must be attached to the container if the package is too small to list ingredients on a label.

On Feb. 7, 1972, FDA originally proposed mandatory cosmetic ingredient labeling when it published 2 proposals in the *Federal Register:* a petition from Professor Joseph A. Page & Consumer Federation of America & a separate FDA proposal. FDA received 291 comments in response to the 2 proposals. Of these, 273 endorsed mandatory cosmetic ingredient labeling.

Details—*Federal Register:* Oct. 17, page 28912; Aug. 11, 1972, page 16208; April 11, 1972, page 7151; Feb. 7, 1972, page 3523. CONSUMER REGISTER: Feb. 15. CONSUMER NEWS: Jan. 1; May 1, 1972.

Cosmetic complaints

Food & Drug Administration (FDA) has established a procedure by which cosmetic manufacturers, packers & distributors may voluntarily notify it twice a year of consumer complaints about cosmetics.

FDA will use the complaint information (1) to pinpoint products, product types & ingredients causing allergic reactions or injuries & (2) to determine if there is a need for the manufacturer to reformulate a cosmetic or if there is a need for other action to protect consumers from harmful cosmetics. Any FDA action based on reports of complaints will come after March 1, 1974—the deadline for manufacturers, packers & distributors to report its consumer complaints for the period July 1 through Dec. 31, 1973.

FDA received 11 comments on its proposal of Nov. 2, 1972, that led to establishing this voluntary procedure. Comments came from a Congressman, 4 consumers, a medical association, 2 public interest groups, a cosmetic company, an industry association & a city official.

Details—*Federal Register:* Oct. 17, page 28914; Nov. 2, 1972, page 23344; Aug. 11, 1972, page 16208. CONSUMER REGISTER: Dec. 1, 1972; Sept. 1, 1972. CONSUMER NEWS: May 1, 1972.

Tire codes

National Highway Traffic Safety Administration (NHTSA) has announced that an updated list of codes assigned to retreaded tire manufacturers is available for purchase or inspection.

The agency's Tire Identification & Record Keeping Regulation requires that new tires be marked with a 2-symbol code & retreaded tires be marked with a 3-symbol code. NHTSA assigns the codes, which for retreaded tries is the first 3 numbers after the letters DOT-R on the tire wall.

The 1973 updated list may be seen or bought as computer tape or computer printout by request to Tire Division, Room 5307, National Highway Traffic Safety Administration, Washington, DC 20590; Attn.: E. H. Wallace.

Details—*Federal Register:* Oct. 17, page 28861; Jan. 11, 1972. CONSUMER NEWS: July 1 & Feb. 1, 1972; June, 1971.

Injectable contraceptive

Nov. 9 is deadline for comments on a Food & Drug Administration (FDA) proposal to require that consumer information leaflets must be included in every package of a drug that the FDA has approved for limited use as an injectable contraceptive.

When injected once every 3 months, the drug (Depo Provera made by The Upjohn Co.) is an effective contraceptive. But since it does have certain risks, FDA has approved its use on a limited basis only—that is, for a specific small group of women who cannot or will not use other contraceptives. FDA approval of the drug is contingent on the manufacturer's agreement to include information in the drug package to tell the patient what risks are involved in using Depo Provera.

These risks include the following:

- Infertility is a possibility. Women taking Depo Provera may, after discontinuing it, be unable to conceive for as long as 31 months or even permanently.
- Breast tumors were observed in test dogs that re-

ceived low & high doses. At high doses, some tumors were cancerous and spread to other organs.

- Monthly periods may become irregular or stop, & unexpected bleeding may occur.

Despite these risks, FDA is following the advice of its **Obstetrics & Gynocology Advisory Committee** to approve Depo Provera because FDA believes that the drug's unique quality—that it need be administered only once every 3 months, rather than daily, as with oral contraceptives—makes it particularly appropriate for "a limited & well-defined patient population" who:

- Refuse or are unable to accept the responsibility demanded by other contraceptive methods;
- Are incapable or unwilling to tolerate the side effects of conventional oral contraceptives; or
- Have used other methods of contraception that have repeatedly failed.

To safeguard patients, the FDA proposal would require that 2 consumer information papers be included in the drug's package. One would be a brief leaflet that the patient must read before the drug is injected by the doctor; this leaflet sums up the risks associated with Depo Provera. If the patient is incompetent to grant her informed consent, her parent or guardian must read the leaflet & consent to use of the drug. The second patient brochure would have to be more detailed & would have to discuss at length the risks & possible side effects associated with the drug. This brochure would be intended to be read at the patient's leisure after the drug has been administered.

Depo Provera already is approved by FDA as an injection in treating cancer of the uterus. It has also been used—since 1965—by some doctors, institutions & birth control clinics for contraception in research programs.

Under the current FDA proposal, all orders for Depo Provera would have to be signed by a doctor. The signed orders would enable FDA to monitor the drug & to notify doctors if there are indications of an increased risk of breast cancer.

Details—*Federal Register:* Oct. 10, page 27940. Send comments to Hearing Clerk, Health, Education, & Welfare Dept., 5600 Fishers Lane, Rockville, MD 20852.

Baggage liability

Nov. 23 is deadline for comments on **Interstate Commerce Commission's** (ICC) proposal that no interstate bus company can limit its liability for lost or damaged baggage to less than $250 for each adult ticket. Current liability is $50 for each bag for each adult ticket.

The $250 liability would apply to baggage checked with buses operating on regular routes or on charter trips. However, a bus's liability could be less than $250 if the passenger does not securely attach an identification tag giving the passenger's name & address.

ICC's proposal would require buses to post signs to inform passengers of baggage liability & the opportunity of paying a fee for liability coverage greater than $250. Buses would have to provide free luggage tags at ticket windows & baggage counters.

Details—*Federal Register:* Oct. 17, page 28843. Send comments to Office of the Secretary, Interstate Commerce Commission, Washington, DC 20423.

X-ray machines

Dec. 10 is deadline for comments on a **Food & Drug Administration** (FDA) proposal for a new standard to protect the public & workers from exposure to certain commercial x-ray machines.

These machines, which are enclosed in cabinets, are commonly used in manufacturing industries to find internal flaws in products as well as by art experts to authenticate works of art. In recent months, these cabinet x-ray systems have been used to detect hijackers' weapons & other contraband in luggage & packages on aircraft & on other commercial carriers.

The proposed standard would limit x-ray emissions to a rate of no more than 0.5 milliroentgen in one hour, at a distance of about 2 inches from the equipment. This proposed maximum rate, according to FDA, would have no adverse health effect on people working with the equipment.

Other proposed provisions would require

- A barrier to be used to avoid having any part of a worker's body enter the primary x-ray beam;
- Each cabinet door to have at least 2 safety interlocks to disconnect the system as the door is opened;
- A locked control to be installed to prevent the machine from operating when the key is removed;
- A control to be available inside walk-in cabinets to prevent x-ray generation by an outside operator;
- Audible & visible x-ray warning signals to be used inside the cabinet & caution labels posted outside.

These proposed standards would apply only to x-ray machines in enclosed cabinets & to the partially enclosed adaptations of cabinet x-ray machines that have been a recent development in airlines' attempts to thwart hijackers. Medical & dental x-ray equipment is already covered by separate standards.

Details—*Federal Register:* Oct. 10, page 28012; Aug. 15, 1972, page 16461. CONSUMER REGISTER: Sept. 15, 1972. Send comments to Hearing Clerk, Food & Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

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